IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS LUFKIN DIVISION

DEBBIE PRESTRIDGE)
Plaintiff))
ν.) Civil Action No. 9:07 CV 157
MERCK & CO., INC.,) JURY TRIAL DEMANDED
Defendant))

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Plaintiff DEBBIE PRESTRIDGE (hereinafter referred to as "Plaintiff"), complaining of MERCK & CO., INC. (hereinafter "Merck" and/or "Defendant") and for cause of action would respectfully show unto the Court and the Jury the following:

INTRODUCTION & PARTIES

- 1. This is a civil action brought on behalf of Plaintiff regarding damages which occurred as a result of Plaintiff's ingestion of FOSAMAX. FOSAMAX was manufactured, marketed, distributed and to Plaintiff by Merck and/or Merck representatives.
- 2. Plaintiff is an individual who is a citizen of the State of Texas and a resident of Sabine County, Texas.
- Jersey, with its principal place of business at One Merck drive, Whitehouse Station, New Jersey 08889. Merck is duly authorized to conduct business in the State of Texas and has and continues to conduct business in this state. Service of process upon Merck may be accomplished by serving the agent for service of process CT Corp. System, 350 N. St. Paul Street, Dallas, Texas

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- 75201. Merck does business in Texas and, on information and belief, at all times relevant advertised, marketed, promoted, sold and/or distributed FOSAMAX in Texas.
- 4. At all times relevant herein, Merck was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease, and other products for use by the mainstream public and, more specifically, Plaintiff.
- 5. Merck either directly or through its agents, apparent agents, servants or employees, at all relevant time, sold and distributed FOSAMAX in the State of Texas. Further, Merck derives substantial revenue from pharmaceutical products used or consumed in the State of Texas.
- 6. Merck placed FOSAMAX into the stream of commerce without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis or jaw bone decay.

JURISDICTION & VENUE

7. The Court has jurisdiction over this lawsuit under 28 U.S.C. §1332(a)(1) because the Plaintiffs and the Defendant are citizens of different states and the amount in controversy exceeds \$75,000, excluding interest and costs.

CONDITIONS PRECEDENT

8. Plaintiff has satisfied all conditions precedent to bringing this action.

FACTS

9. Merck, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, and sold FOSAMAX for

the treatment of osteoporosis, Paget's Disease, and other uses. At the time the drug was placed into the stream of commerce, it was dangerously defective in a number of respects.

- 10. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested the drug, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw or significant jaw bone decay.
- 11. Merck concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.
- 12. Merck failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
- 13. The FDA even recommended and stated that the labeling for FOSAMAX be amended by Merck to specifically warn about the risks of osteonecrosis. Despite such, Merck refused to heed the FDA's request for over one year. Instead, it continued to defend the drug, mislead the public, including Plaintiff, and minimized findings.
- 14. Plaintiff was prescribed and began taking FOSAMAX in approximately 2002. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner. As a direct and proximate result, Plaintiff has suffered severe injury and damages, including osteonecrosis, pain, anguish, and other related damages. Plaintiff will continue to suffer from her injuries and will require continued medical treatment for same.

ALLEGATIONS

15. Merck endeavored to deceive Plaintiff, and the general public, by not disclosing the findings of the various studies which revealed problems concerning the dangers of osteonecrosis or jaw bone decay with their drug FOSAMAX.

- 16. Further, Merck did not provide warnings and instructions that would have put Plaintiff, and the general public, on notice of the dangers and adverse effects caused by FOSAMAX.
- 17. Merck designed, manufactured, distributed, sold and/or supplied FOSAMAX into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiff and the general public.
- 18. FOSAMAX as designed, manufactured, distributed, sold and/or supplied by Merck was defective as marketed due to inadequate warnings, instructions and/or labeling.
- 19. FOSAMAX as designed, manufactured, distributed, sold and/or supplied by Merck was defective due to inadequate testing before and after Merck's knowledge of the various studies evidencing the rightful concerns over the risks of osteonecrosis and jaw bone related injuries associated with FOSAMAX.
- 20. Plaintiff would not have used and/or would have ceased to use FOSAMAX had Merck properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

21. The nature of the Plaintiff's injuries and their relationship to FOSAMAX use were inherently undiscoverable; and, consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the existence of her claims against Defendants. Plaintiff did not discover, and through the exercise of reasonable care and due diligence, could not have discovered, her injuries earlier.

- 22. Further, Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendant's tortious conduct. Under appropriate application of the "discovery rule," Plaintiff's suit was filed well within the applicable statutory limitations period.
- 23. Defendant is estopped from asserting a statute of limitations defense because it fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and FOSAMAX.

CAUSES OF ACTION

I. STRICT PRODUCTS LIABILITY

24. Merck is liable as the manufacturer, distributor and/or seller of FOSAMAX because FOSAMAX, when sold, was in a defective and unreasonably dangerous condition. Merck owed a strict duty to Plaintiff not to harm Plaintiff through the use of its drugs.

A. DESIGN DEFECT

- 25. FOSAMAX was defective in design and/or formulation in that, when it left the hands of Merck and/or its representatives, the foreseeable risks of serious harm posed by the drugs outweighed their alleged benefits. The foreseeable risks of serious harm were so great that Plaintiff, and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested FOSAMAX.
- 26. FOSAMAX was placed into the stream of commerce by Merck acting through authorized agents, servants, employees and/or representatives. Plaintiff was prescribed FOSAMAX by Plaintiff's physician and used the drugs in a manner reasonably foreseeable by Merck.

27. The FOSAMAX ingested by Plaintiff was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. As a result of the use of FOSAMAX, Plaintiff suffered severe, permanent and disabling injuries and related damages.

B. MARKETING DEFECT-INADEQUATE AND IMPROPER WARNINGS

- 28. FOSAMAX was marketed to physicians to be prescribed to their patients and were marketed and advertised directly to the consuming public. FOSAMAX as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drugs. Further, Merck failed to warn of the serious risks associated with their drug after it had knowledge of same. The information provided to consumers did not reflect Merck's knowledge that FOSAMAX was not safe and effective as indicated in its aggressive marketing campaigns, nor were consumers made aware that ingesting the drugs could result in serious injury, pain and discomfort and/or death. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or sudden death due to the ingestion of FOSAMAX should have been disclosed by Merck.
- 29. Plaintiff was prescribed FOSAMAX by Plaintiff's physician who used the drug in a manner reasonably foreseeable by Merck. FOSAMAX was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. Plaintiff was not aware of, and could not have reasonably discovered, the unreasonably dangerous nature of FOSAMAX.
- 30. As the producing cause and legal and direct result of the failure to warn consumers of the defective condition of FOSAMAX, as manufactured and/or supplied by Merck,

and its representatives, Plaintiff has suffered severe, permanent and disabling injuries and related damages.

II. FRAUD

- 31. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges:
- 32. Merck fraudulently represented to the general public, as well as healthcare professionals, that FOSAMAX was a safe and effective drug. It also represented that the drug was safer than alternative medications. Defendant knew these representations were false, yet willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of FOSAMAX to consumers, including Plaintiff, and the medical community.
- 33. Defendant made these representations while knowing that, if healthcare professionals and consumers knew of the serious risks associated with the ingestion of FOSAMAX, they would not prescribe and/or ingest this drug. Defendant knew its representations to be false, and Plaintiff relied on Defendants' false representations in her ingestion of these drugs. These fraudulent representations by Defendant was a proximate cause of the injuries to and monetary losses of Plaintiff.
- 34. Additionally, Merck fraudulently withheld and concealed information about the substantial risks of osteonecrosis with using FOSAMAX. Further, Merck intentionally concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market, despite its false representations to the contrary.
- 35. Plaintiff relied upon Merck's fraudulent misrepresentations and concealment to her detriment.

III. NEGLIGENCE

- 36. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further allege:
- 37. Merck owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX. Merck breached this duty in one or more of the following respects:
 - a) Failing to properly and thoroughly test FOSAMAX before releasing the drug into the stream of commerce;
 - b) Failing to properly and thoroughly analyze the data resulting from premarketing tests of FOSAMAX;
 - c) Failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
 - d) Designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could forseeably occur as a result of using the drug;
 - e) Failing to exercise due care when advertising and promoting FOSAMAX;
 - f) Negligently continuing to manufacture, market, advertise, and distribute FOSAMAX with any warnings about osteonecrosis or jaw bone decay even after Defendant knew or should have known of its adverse effects;
 - g) And others as might be shown at trial.

38. As a direct and proximate result of Merck's actions, omissions, and misrepresentations, Plaintiff suffered severe painful injuries requiring extensive medical treatment and damages.

IV. NEGLIGENT MISREPRESENTATION

- 39. Merck failed to communicate to Plaintiff and the general public that the ingestion of FOSAMAX could cause serious injuries after it became aware of such risks. Instead, Merck represented in their marketing that FOSAMAX was safe and effective.
- 40. Plaintiff brings this cause of action against Merck under the theory of negligent misrepresentation for the following reasons:
 - Merck individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about FOSAMAX, in that it made such misrepresentations when it knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Merck made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
 - The above misrepresentations were made to Plaintiff, as well as the general public;
 - Plaintiff justifiably relied on Merck's misrepresentations; and
 - Consequently, Plaintiff ingested FOSAMAX to Plaintiff's detriment. Merck's respective negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

V. MISREPRESENTATION

41. Merck is engaged in the business of selling FOSAMAX. By its advertising, labels, or otherwise, Merck has made to Plaintiff, and the public, misrepresentations of a material fact concerning the character or quality of FOSAMAX.

42. Plaintiff justifiably relied on Merck's misrepresentations in purchasing FOSAMAX. Plaintiff has suffered physical harm proximately caused by Merck's misrepresentations regarding the character or quality of FOSAMAX.

VI. EXPRESS WARRANTY

- 43. Plaintiff restated all allegations in this complaint as if fully set forth herein.
- 44. Merck expressly represented to Plaintiff and other consumers that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, such as osteonecrosis, and that it was adequately tested.
- 45. FOSAMAX does not conform to Merck's express representations because it is not safe, has numerous and seriously dangerous side effects, and causes severe and permanent injuries.
- 46. At all relevant times, FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner as Plaintiff did.
- 47. Plaintiff relied upon Defendant's express warranties. As a direct and proximate result, Plaintiff suffered severe injuries and monetary loss.

VII. IMPLIED WARRANTY

A. WARRANTY OF MERCHANTABILITY

48. Merck is a merchant and/or sellers of FOSAMAX. Plaintiff purchased FOSAMAX from Merck and used it for the ordinary purpose for which it is used by consumers. At the time it was purchased by Plaintiff, FOSAMAX was not fit for the ordinary purpose for which such drugs are used. Specifically, FOSAMAX was not fit for the ordinary purpose for which such drug is used because it was not manufactured, designed or marketed in a manner to

accomplish its purpose safely. Merck's breach of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

B. WARRANTY OF FITNESS

- 49. Merck sold FOSAMAX to Plaintiff with the knowledge that Plaintiff was purchasing said drug for a particular purpose. Further, Merck knew, or should have known, that Plaintiff was relying on Merck's skill or judgment to select goods fit for Plaintiff's purpose.
- 50. Merck delivered goods that were unfit for Plaintiff's particular purpose, and thus breached its implied warranty of fitness. Plaintiff has notified Merck of Merck's breach of its implied warranty of fitness.
- 51. Merck's failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's injuries and monetary losses.

DAMAGES

52. Upon the trial of this case, it will be shown that Plaintiff was caused to sustain serious injuries and damages as a proximate result of Defendants' conduct. Plaintiff will respectfully request the Court and Jury to determine the amount of the loss Plaintiff has incurred in the past and will incur in the future, not only from a financial standpoint, but also in terms of good health and freedom from pain and worry.

PUNITIVE DAMAGES

53. At all times relevant hereto, Merck actually knew of the defective nature of FOSAMAX as set forth herein and continued to design, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable serious harm caused by the drugs. Merck's conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will,

recklessness, and/or willful and intentional disregard for the safety and rights of Plaintiff, as well as the general public and/or consumers. Plaintiff is therefore entitled to punitive damages.

JURY DEMAND

54. Plaintiff hereby requests a trial by jury on all issues in this case.

RELIEF SOUGHT

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that upon trial hereof, the Court grant:

- 1. Judgment against Defendant for actual damages, as set forth above, in an amount in excess of the minimum jurisdictional limits of this Honorable Court;
- 2. Interest on said Judgment, at the legal rate from the date of the Judgment;
- 3. Plaintiff's costs of this suit;
- 4. Prejudgment interest as allowed by law;
- 5. Any additional damages and punitive damages under the facts set forth in this or any amended pleading(s); and
- 6. Such other and further relief to which Plaintiff be justly entitled, both in law and in equity.

Respectfully submitted,

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